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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,029	03/22/2004	Carl E. Griffin	2G02.I-091	9999
23506	7590	01/23/2007	EXAMINER	
GARDNER GROFF SANTOS & GREENWALD, P.C.			EREZO, DARWIN P	
2018 POWERS FERRY ROAD			ART UNIT	PAPER NUMBER
SUITE 800			3731	
ATLANTA, GA 30339				
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/23/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/806,029.	GRiffin ET AL.
	Examiner Darwin P. Erezo	Art Unit 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 22 March 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>8/10/04</u> .	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 8/10/04 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3, 4, 9-16 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 3 recites the limitation "the drive member stop" in lines 1 and 3-4. There is insufficient antecedent basis for this limitation in the claim. The applicant is suggested to replace said limitation with either "drive member stop member" or "stop member of the drive member".

This limitation is also recited in claims 4, 9 and 19.

5. Claim 4 recites the limitation "the lancet stop" in line 2. There is a lack of antecedent basis for the limitation in the claim. The applicant is suggested to use similar language as provided above.

This limitation is also recited in claim 9.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-5, 7, 9, 10, 12, 13 and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US 55,69,287 to Tezuka et al.**

(claim 1) Tezuka discloses a lancet device comprising a lancet **205** that is movable between a retracted position (Fig. 2) and an extended position (Fig. 3); and a drive member **133** that impacts the lancet to drive the lancet from the retracted position to the extended position, wherein the drive member is decoupled from the lancet when the lancet is in the extended position (and after the drive member rams the lancet, as shown in Fig. 4).

(claim 2) Fig. 3 shows a stop member located in the cylinder **100** for limiting the travel of the drive member before the lancet reaches the fully extended position.

(claims 3 and 4) The stop member for the drive member does not limit the travel of the lancet. Instead, coil spring **206** and edge **203a** limits the travel of the lancet, which is a separate structure from the stop member of the drive member.

(claim 5) The drive **133** member is a piston.

(claim 7) There is a trigger latch **117** removably received in a notch **136** in the drive member.

(claim 9) See the rejections to claims 1-4.

(claim 10) See the rejection to claim 5.

(claim 12) See the rejection to claim 7.

(claim 13) There is a manual cocking mechanism for moving the drive member to the retracted position (col. 4, lines 27-34).

(claim 16) Before the drive member impacts the lancet, it has kinetic energy stored, as shown in Fig. 2. The lancet at this configuration does not have kinetic energy. Once the drive member is released, it uses the stored kinetic energy to impact the lancet so that the lancet has kinetic energy while the drive member loses its kinetic energy.

(claim 17) Tezuka discloses a method of lancing skin to sample body fluid, comprising the steps of: impacting a lancet **205** with a drive member **133** to move the lancet from a retracted position (Fig. 2) to an extended position (Fig. 3), and decoupling the lancet from the drive member (Fig. 4).

(claim 18) The drive member impacts a drive member stop, as recited in the rejection to claim 2 above.

(claim 19) The lancet member impacts a lancet member stop, as recited in the rejection to claim 3 above.

(claim 20) Tezuka provides a lancing device comprising both the lancet and the drive member.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3731

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claims 6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tezuka et al. and in view of US 5,368,047 to Suzuki et al.**

Tezuka discloses all the limitations of the claim, including a drive spring 141 but is silent with regards to the drive spring having a proximal end that is closer to the lancet than a distal end of the drive member. However, Suzuki discloses a similar lancet device having a drive member 3 and a drive spring 9; wherein the drive spring has a proximal end that is closer to the lancet than a distal end of the drive member (Fig. 9). That is, the spring 9 encircles the drive member 3, which inherently provides structural rigidity and prevents lateral movement of the drive member. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the drive member of Tezuka to include an opening for receiving the drive spring, so that the proximal end of the drive spring is closer to the lancet than the distal end of the drive member, because it would prevent lateral movement of the drive member by providing structural rigidity to the device.

**11. Claims 8, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tezuka et al. and in view of US 6,558,402 to Chelak et al.**

(claims 8 and 14) Tezuka discloses all the limitations of the claims except for a rotatable endcap for adjusting a penetration depth of the lancet. However, Chelak discloses an adjustable endcap for a lancing device, wherein rotation of a portion of the endcap adjusts the penetration depth of a lancet within the endcap (col. 4, lines 49-60). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Tezuka to include the adjustable endcap of Chelak because it would allow the user to adjust the penetration depth of the lancet.

(claim 15) Chelak discloses an inner cap and an outer cap, wherein the outer cap has a helical channel having indentations for receiving a protrusion **349** from the inner cap (Fig. 7). This is the reverse of what is being recited in claim 15. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the inner cap comprising the helical channel and the outer cap comprising the protrusion since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Gazda*, 219 F.2d 449, 104 USPQ 400 (CCPA 1955).

***Conclusion***

**12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Darwin P. Erezo  
Examiner  
Art Unit 3731

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